

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Philippe ROUANET *et al.*

Title: **PERCUTANEOUS COMPOSITION COMPRISING  
4-HYDROXY TAMOXIFEN (as amended)**

Appl. No.: 10/734,638

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Art Unit: 1617

Confirmation 9056

Number:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132**

The undersigned inventors of the subject matter claimed in U.S. Application Serial No. 10/734,638 ("the captioned application"), Dominique Salin Drouin and Jacques Wepierre, do hereby declare and state as follows:

1. We are the inventors of the subject matter recited in the currently pending claims, *e.g.*, a pharmaceutical composition comprising about 0.001% to 1.0 % by weight of 4-hydroxy tamoxifen, about 0.5% to 2% by weight of isopropyl myristate, about 65% to 75% by weight of alcohol, about 20% to 35% by weight of aqueous vehicle, about 1.0% to 5% by weight of gelling agent, wherein the percentage of components are weight to weight of the composition.

2. U.S. Patent Publication No. 2004/0138314, corresponding to U.S. Patent 7,485,623, is directed to methods of reducing breast density using a percutaneous 4-hydroxy tamoxifen composition. U.S. Patent Publication No. 2004/0138314 describes 4-hydroxy tamoxifen compositions within the scope of the pending claims, for example in Table 1.

3. U.S. Patent Publication No. 2004/0138314 is commonly owned with the captioned application, by Laboratoires Besins International SA. The 4-hydroxy tamoxifen compositions within the scope of the pending claims that are disclosed in U.S. Patent Publication No. 2004/0138314 were derived from the undersigned inventors, and were not invented by the inventor of U.S. Patent Publication No. 2004/0138314, Jay Bua.

4. U.S. Patent Publication No. 2005/0032909 is directed to methods of treating mastalgia using a percutaneous 4-hydroxy tamoxifen composition. U.S. Patent Publication No. 2005/0032909 describes 4-hydroxy tamoxifen compositions within the scope of the pending claims, for example in Table 1.

5. U.S. Patent Publication No. 2005/0032909 is commonly owned with the captioned application, by Laboratoires Besins International SA. The 4-hydroxy tamoxifen compositions within the scope of the pending claims that are disclosed in U.S. Patent Publication No. 2005/0032909 were derived from the undersigned inventors, and were not invented by the inventor of U.S. Patent Publication No. 2005/0032909, Bruno de Lignieres.

6. Each of the undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the above-referenced application or any patent issuing thereon.

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Dominique Salin Drouin

Date



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Jacques Wepierre

Date

